Remarks

This Amendment is submitted in response to an Office Action mailed on March 17, 2005, and also submitted in connection with a Request for Continued Examination (RCE) filed concurrently herewith. By this amendment, Claims 1 and 40 have been amended, and Claims 10-39 have been cancelled. Thus, upon entry of this amendment, claims 1-10 and 40-49 will be in the present application. The amendments made herein to the claims do not incorporate new matter into the application as originally filed. Support for the amendments can be found in the drawings and throughout the specification (see Paragraph 55, Line 6).

As an initial matter, it should be noted that the present invention as now amended is directed to a delivery device for introducing a substance directly at least via a side-port into selected region(s) of the skin at pressures less than 5psi. Such systems are desirable in order to accurately place a deposit of substance within the skin as well as to reduce the delivery pressure to the skin. The side-ported device may be supplied from a removable external reservoir, such as a syringe. Additionally, it is desirable to have a system that is able to selectively deliver a substance to the skin such that there would be reduced leakage from both the skin and the device when the system is pressurized from the connection of needle to reservoir. The device of the instant application includes a needle and at least one outlet positioned perpendicular to the insertion axis of the needle. The needle has a specific length and outlet placement for directing said substance under pressure from the reservoir into the skin. As has been discovered, the threshold pressures involved with delivery to the skin are much higher than the pressures to deliver to other tissues, and therefore a system according to the present invention, capable of lowering delivery pressures, is required to deliver to the skin without adverse effects such as leakage from the connections to the device.

Applicant's Response to the 37 C.F.R. 1.75(d) Objection to the Specification

The Examiner has objected to the specification as evoking means-plus-function language to define the invention. The Examiner has required the specification be amended pursuant to 37 C.F.R. 1.75(d) and M.P.E.P. section 608.01(o) to explicitly state, with reference to the terms and phrases of the claim element, what structure, materials, and acts perform the function recited in the claim element. Applicant respectfully submits that the specification at paragraphs 40 and 45 do set forth representative structure, materials and acts which perform the function recited in the claim elements. Exemplary penetration limiting means set forth in the aforementioned paragraphs comprise a hub, or needle holder, along with a surface of the infusion device. Furthermore, Applicants respectfully submit that Claim 40 as amended conforms to 37 C.F.R. 1.75(d) and M.P.E.P. section 608.01(o) and respectfully requests reconsideration and withdrawal of the objection.

In the Office Action, the Examiner has made a final rejection of Claims 1-10, and 40-49 under 35 U.S.C. §102(e) or in the alternative 35 U.S.C. §103(a) over U.S. Pat. No. 6,314,317 to Willis (hereinafter "Willis). Applicants respectfully traverse that rejection. Willis discloses a drug delivery device having a member (13) needle-like device having a plurality of pores (14). Although the drawing in FIG. 2 of Willis may appear to show side ports of the Applicant's invention, a closer reading of Willis shows that the pores of Willis **are one to two orders of magnitude smaller than the side ports of the applicant's invention and are not continuously open to flow.** Moreover, the pores (14) of Willis are designed to be implemented at high densities, that is, an extremely large number of pores per unit area, which would impede flow.

From Willis Col 5, lines 46-51:

> The diameter of the pore can be chosen such that, when coated with an electroactive polymer in an uncharged state, it can be open. The diameter of the pores within the membrane (or within any other material used as a member) can vary, e.g., from about 0.1

micrometer to about 10 micrometers (e.g., from about 1.0 micrometer to about 8.0 micrometers, such as from about 4.0 micrometer to about 6.0 micrometers).

And Col 5, lines 60-63:

In certain embodiments, the pore density can range from about 1 x 10^5 pores per square centimeter to about 3 x 10^8 pores per square centimeter.

Although the drawing in FIG. 2 of Willis may appear to show side ports, as discussed in MPEP § 2125,when the reference does not disclose that the drawings are to scale and is silent as to dimensions, rejections based on measurement of the drawing features are improper. *See Hockerson-Halberstadt, Inc. v. Avia Group Int'l, 222 F.3d 951, 956, 55 USPQ2d 1487, 1491 (Fed. Cir. 2000).* In fact, the disclosure of Willis shows that the pore densities are orders of magnitude higher than shown in the drawing. Moreover, the pores (14) of Willis are designed to be place in the patient's subcutaneous tissue (Col 4, Lines 55-56). Willis contains no teaching of bi-phasic delivery. In contrast, the Applicant's side port is adapted to be placed in the skin *inter alia* intradermally and/or epidermally, with pore densities *seven to eight orders of magnitudes* less than Willis. Furthermore, Applicant's invention does encompass delivery to two distinct locations within the skin.

It is axiomatic that anticipation of a claim under § 102 can be found only if the prior art reference discloses every element of the claim. Each of independent claims 1 and 40 includes a side port, a specified pressure range, and a prescribed penetration depth. Therefore, for Willis to anticipate the claims; Willis must disclose each of the above noted elements. Moreover, Willis contains neither teaching nor suggestion of a side ported needle of the type as now recited in Applicants' amended claims for delivery to the skin at low pressures. Thus, applicants respectfully submit that the Examiner's rejection of the claims as anticipated by Willis is no longer tenable, and respectfully request withdrawal of that rejection.

In the Office Action, the Examiner has rejected final rejection of Claims 1-10, and 40-49 under 35 U.S.C. §103(a) as unpatentable over Willis. Willis is a system for subcutaneous injection. Additionally, Willis does not consider intradermal injections and the problems and requirements to inject intradermally *inter alia* higher pressures. The

aspects of the Applicant's invention lie in the discovery of the source of a problem of higher delivery pressures in delivery to the shallow depths of the skin *inter alia* intradermal delivery; even though the remedy may have been obvious once the source of the problem is identified. This is part of the 'subject matter as a whole', which should always be considered in determining the obviousness of an invention under 35 U.S.C. § 103. *In re Sponnoble*, 405 F.2d 578, 585, 160 USPQ 237, 243 (CCPA 1969).The Claims, as amended, require outlets sized for a specific pressure threshold, in contrast to the pores of Willis which are far smaller than the outlets of the Applicant's invention.

Willis provides no motivation to modify the depth of the delivery or the configuration of the outlets for delivery into the skin at the specific depths claimed. The examiner has stated "*It is the Examiner's position that the various ranges taught by applicant, and clearly disclosed and encompassed by Wills*[sic], *would be clearly understood by someone of ordinary skill in the art. Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify the device of Wills* [sic] *to vary the various dimensions as set forth in the claims...*" The Examiner should note, according to MPEP§2143.02, a statement that modifications of the prior art to meet the claimed invention would have been "well within the ordinary skill of the art at the time the claimed invention was made" because the references relied upon teach that all aspects of the claimed invention were individually known in the art is ***not sufficient to establish a prima facie case of obviousness without some objective reason to modify the teachings*** of the reference(s). *Ex parte Levengood*, 28 USPQ2d 1300 (Bd. Pat. App. & Inter. 1993). See also *In re Kotzab*, 217 F.3d 1365, 1371, 55 USPQ2d 1313, 1318 (Fed. Cir. 2000). The claims as now amended have specific size and pressure limitations which are not taught or suggested by Willis, or any of the references cited by the examiner. The examiner may not appropriately rely on "the level of skill in the art" to provide the suggestion to make modifications to the Willis device.

Additionally, the device of Willis was intended as a controlled release matrix having an electro active polymer. Willis is silent as to the both the general and precise dimensions of the needles to effect delivery to the skin (intradermally and/or epidermally). Additionally, the pores of Willis are switchable to facilitate regulation of flow, which creates an additional pressure head, which may be presumed to add to the

pressures of delivery to the skin in the use of the Willis device. The Examiner should note, according to MPEP §2143.02, that if a proposed modification would render the prior art invention modified unsatisfactory for its intended purpose, then there is no suggestion or motivation to make the proposed modification. *In re Gordon*, 733 F.2d 900, 221 USPQ 1125 (Fed. Cir. 1984). In contrast, the needles of the Applicant's invention have outlet(s) sized for delivery to the skin, and at the specific tissue depths required for delivery to the skin. Therefore, the current limitation in Claims 1 and 40, as now amended, would be a modification of Willis, which would render the device of Willis unsatisfactory for its intended purpose.

Conclusion

In view of the Remarks above, applicant respectfully submits that Claims 1-10 and 40-49 are clearly in condition for allowance, and respectfully requests that the Examiner earnestly reconsider the rejections of the present application. Applicant hereby authorizes the Commissioner to charge the fees necessary in connection with this Response, the RCE, and any other fees necessary in connection with this application, to Deposit Account Number 02-1666.

In light of the above amendments and remarks, Applicant respectfully requests that the Examiner enter the amendments and consider the remarks made herein. Consideration and prompt allowance of the claims are respectfully submitted.

Any questions concerning this application or amendment may be directed to the undersigned agent of applicant.

Respectfully submitted,

By: _____

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Robert E. West
Reg. No. 48,030
Agent for Applicants
(201) 847-6782

Becton, Dickinson and Company
1 Becton Drive
Franklin Lakes, NJ 07417-1880
Fax : 201-847-5377